**FOOD AND DRUG ADMINISTRATION (FDA)**
**Center for Drug Evaluation and Research (CDER)**

*Joint Meeting of the Pulmonary-Allergy Drugs Advisory Committee (PADAC) & the Drug Safety and Risk Management Advisory Committee (DSaRM)*

Hilton Washington, DC North/ Silver Spring
8727 Colesville Road, Silver Spring, MD
March 10-11, 2010

AGENDA

The Committees will discuss the design of medical research studies (known as "clinical trial design") to evaluate serious asthma outcomes (such as hospitalizations, a procedure using a breathing tube known as intubation, or death) with the use of the class of asthma medications known as long acting beta-2 adrenergic agonists (LABAs) in the treatment of asthma in adults, adolescents, and children.

**-DAY ONE- March 10, 2010**

| | | |
|---|---|---|
| 8:00 a.m. | Call to Order<br>Introduction of Committee | **Eric Swenson, M.D.**<br>Acting Chair, PADAC |
| | Conflict of Interest Statement | **Kristine Khuc, Pharm.D.**<br>Designated Federal Official, PADAC |
| 8:15 a.m. | Opening Remarks | **Curtis Rosebraugh, M.D.**<br>Director, Office of<br>Drug Evaluation II<br>Center for Drug Evaluation and Research (CDER)<br>FDA |
| 8:20 a.m. | **FDA Presentation**<br>Background and Trial Design Considerations | **Badrul Chowdhury, M.D., Ph.D**<br>Director, Division of<br>Pulmonary and Allergy<br>Products<br>CDER, FDA<br><br>**Ann McMahon, M.D.**<br>Deputy Director,<br>Division of Pharmacovigilance I<br>Office of Surveillance and<br>Epidemiology, CDER, FDA<br><br>**Andrew Mosholder, M.D.**<br>Medical Officer, Division of<br>Epidemiology, Office of Surveillance and Epidemiology, CDER, FDA |
| | Statistical Considerations | **Benjamin Neustifter, Ph.D.**<br>Mathematical Statistician<br>Office of Biostatistics, Division VII<br>CDER, FDA |
| 9:50 a.m. | Questions to FDA for Clarification | |
| 10:05 a.m. | Break | |
| 10:20 a.m. | **FDA Presentation, cont.** | |

*-Agenda cont..-*

| | | |
|---|---|---|
| | Drug Use Data | **Grace Chai, Pharm.D.**<br>Drug Utilization Analyst<br>Division of Epidemiology<br>Office of Surveillance and Epidemiology, CDER, FDA |
| | Summary/Questions | **Badrul Chowdhury, M.D., Ph.D.**<br>Director, Division of Pulmonary and Allergy Products, CDER, FDA |
| 10:45 a.m. | Questions to FDA for Clarification | |
| 11:00 a.m. | **Sponsor Presentation**<br>Evaluating Serious Outcomes in Asthma When LABA is Added to Inhaled Corticosteroid (ICS): Study Design Approaches | **GlaxoSmithKline**<br>**Katherine Knobil, M.D.**<br>GlaxoSmithKline<br>Vice President, Respiratory Medicines Development Centre |
| | Study Design Considerations For Rare Asthma-related Events | |
| | Role of Observational Study Methods: Proposed Study | **Carlos Camargo, M.D., Dr.P.H.**<br>Massachusetts General Hospital<br>Harvard Medical School |
| | Conclusions and Recommendations | **Katherine Knobil, M.D.**<br>GlaxoSmithKline<br>Vice President, Respiratory Medicines Development Centre |
| 12:15 p.m. | Lunch | |
| 1:15 p.m. | Questions to Sponsor for Clarification | |
| 1:30 p.m. | **Sponsor Presentation**<br>Design and Feasibility Assessments for a Postmarketing Safety Study for Symbicort | **AstraZeneca**<br>**Catherine Bonuccelli, M.D.**<br>Therapeutic Area Clinical Vice President, Respiratory & Inflammation<br>AstraZeneca<br><br>**Kevin Carroll, M.Sc.**<br>VP Statistics & Chief Statistician<br>AstraZeneca<br><br>**Tomas Andersson, M.D., Ph.D.**<br>Medical Science Director, Symbicort<br>AstraZeneca |

**FOOD AND DRUG ADMINISTRATION (FDA)**
**Center for Drug Evaluation and Research (CDER)**
*Joint Meeting of the Pulmonary-Allergy Drugs Advisory Committee (PADAC) & the Drug Safety and Risk Management Advisory Committee (DSaRM)*
Hilton Washington, DC North/ Silver Spring
8727 Colesville Road, Silver Spring, MD
March 10-11, 2010

*-Agenda cont.-*

| | | |
|---|---|---|
| 2:45 p.m. | Questions to Sponsor for Clarification | |
| 3:00 p.m. | Break | |
| 3:15 p.m. | **Sponsor Presentation**<br>Regulatory History | **Novartis**<br>**Peter Fernandes, M.Pharm.**<br>Vice President, Drug Regulatory Affairs, Respiratory<br>Novartis |
| | Foradil Safety in Asthma:<br>Study Proposal | **Steve Pascoe, MBBS, M.Sc.**<br>Clinical Science Unit Head, Respiratory<br>Novartis |
| 4:30 p.m. | Questions to Sponsor for Clarification | |
| 5:00 p.m. | Adjourn | |

**-DAY TWO- March 11, 2010**

| | | |
|---|---|---|
| 8:00 a.m. | Call to Order<br>Introduction of Committee | **Eric Swenson, M.D.**<br>Acting Chair, PADAC |
| | Conflict of Interest Statement | **Kristine Khuc, Pharm.D.**<br>Designated Federal Official, PADAC |
| 8:15 a.m. | Welcome Remarks | **Curtis Rosebraugh, M.D.**<br>Director, Office of Drug Evaluation II<br>CDER, FDA |
| 8:20 a.m. | Open Public Hearing | |
| 9:20 a.m. | Questions for Clarification | |
| | Committee Deliberations | |
| 10:30 a.m. | Break | |
| 10:45 a.m. | Continue Committee Deliberations | |
| 11:45 a.m. | Lunch | |
| 1:00 p.m. | Continue Committee Deliberations | |
| 4:00 p.m. | Adjourn | |